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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,776	03/07/97	CAVALIERE VESELY	R 7063-001-0

022850 HM22/0307
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EXAMINER	
MINNIFIELD, N	
ART UNIT	PAPER NUMBER

1645

18

DATE MAILED: 03/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/813,776

Applicant(s)

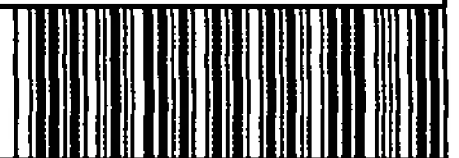
VESELY ET AL

Examiner

N. M. Minnifield

Group Art Unit

1645



☒ Responsive to communication(s) filed on Dec 21, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 37-44 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 37-44 is/are rejected.

☒ Claim(s) 38-44 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413 (2)

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

Takahashi et al already of record

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Amendment

1. Applicants' amendment after final (12/6/99; 12/21/99) have been entered. Claims 37-44 are now pending. It is noted that finality of the last Office action has been withdrawn. A new NONFINAL Office Action is set forth below. During an interview (3/1/00) an agreement with regard to claim language (--a culture of bacteria strain--) for claim 37 was reached. However, upon review and further consideration this language is not found sufficient and the following rejections are set forth. Any inconvenience is truly regretted.
2. Claims 38-44 are objected to because of the following informalities: spelling error, "Pasterur". Appropriate correction is required.
3. Claims 37-44 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The product, as claimed, has the same characteristics and utility as that found in nature. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology "essentially purified and isolated" (i.e. if such purity is supported in the

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specification) and/or a description of what applicant's protein is "free of" relative to the natural source which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

It is suggested that Applicants use "A biologically pure..."

4. It is noted that the claims recite a gram-positive bacteria strain characterized by exhibiting: less than 50% 7 -dehydroxylase activity and less than 50% bile acid deconjugation activity and that the bacteria strain belong to *Streptococcus thermophilus* or *Lactobacillus bulgaricus*. Activity of less than 50% (i.e. 0% to 50%) is encompassed by or is anticipated by prior art that teaches, discloses or suggests no 7 -dehydroxylase activity and bile acid deconjugation activity; or the reference is silent with regard to these activities.

5. Claims 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al 1994, in light of Salvioli et al.

Takahashi et al 1994 disclosed that *Streptococcus thermophilus* had no 7 -dehydroxylase activity on bile acids and that none of the tested strains showed production of either deoxycholic acid or 7-keto-deoxycholic acid (abstract; tables

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2 and 3; p. 3283). If there is no dehydroxylase activity, then there is no bile acid deconjugation.

With regard to the dehydroxylase activity, it is noted that Salvioli et al disclose that "[U]nder normal conditions the deconjugation of bile acids occurs in the large bowel and perhaps in the terminal ileum; unconjugated bile acids entering the large bowel are 7 -dehydroxylated by anaerobic bacteria to yield secondary bile acids." (p. 80, col. 1). The secondary bile acids are dehydroxylated by dehydroxylase.

The claimed invention is anticipated by the prior art of Takahashi et al.

The prior art, Takahashi et al, anticipates the claimed invention by disclosing the bacterial strains with the same or similar characteristics as claimed. The bacterial strains in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the bacterial strains of Takahashi et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the bacterial strains of the prior art are evidenced to meet the limitations of the claimed bacterial strains, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' bacterial strains with the bacterial strains of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed

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product and the product of the prior art (i.e., that the bacterial strains of the prior art does not possess the same material structural and functional characteristics of the claimed bacterial strains) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Determination of characteristics which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

6. Claim 37-44 are rejected under 35 U.S.C. 102(b, d, or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saito et al (5516684 or EP 0671468) in light of Salvioli et al.

It is noted that Saito et al (5516684) is rejected under 102(e) and Saito et al (EP 0671468) is rejected under 102(b or d).

Saito et al (5516684), for example, disclose a gram positive bacterial strain which does not exhibit deconjugation of bile acids (abstract). Saito et al also disclose bacteria that "...exhibits lowering of cholesterol in blood without exhibiting deconjugation of bile acids, thereby not forming secondary bile acids..." (col. 2, l. 46-50). The bacteria do not produce the secondary bile acids since the bacteria do not exhibit deconjugation of bile acids (col. 5); therefore there is no dehydroxylase activity.

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With regard to the dehydroxylase activity, it is noted that Salvioli et al disclose that "[U]nder normal conditions the deconjugation of bile acids occurs in the large bowel and perhaps in the terminal ileum; unconjugated bile acids entering the large bowel are 7 -dehydroxylated by anaerobic bacteria to yield secondary bile acids." (p. 80, col. 1). The secondary bile acids are dehydroxylated by dehydroxylase.

The claimed invention is anticipated by the prior art of Saito et al. The prior art, Saito et al, anticipates the claimed invention by disclosing the bacterial strains with the same or similar characteristics as claimed. The bacterial strains in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the bacterial strains of Saito et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the bacterial strains of the prior art are evidenced to meet the limitations of the claimed bacterial strains, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' bacterial strains with the bacterial strains of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the bacterial strains of the prior art does not possess the same material structural and functional

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characteristics of the claimed bacterial strains) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Determination of characteristics which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

This rejection is maintained for the reasons of record. Applicant's arguments filed April 26, 1999 have been fully considered but they are not persuasive. Applicants have asserted that "...dehydroxylation may occur without deconjugation". The reference states that it may occur, not that it definitely does not occur.

This rejection is maintained for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive. Applicants have asserted that the prior art only refers to *Streptococcus thermophilus* or *Lactobacillus bulgaricus* with regard to being an addition to preparing fermented milk. However, it is noted that the claims recite a gram-positive bacteria strain characterized by exhibiting: less than 50% 7 -dehydroxylase activity and less than 50% bile acid deconjugation activity and that the bacteria strain belong to *Streptococcus thermophilus* or *Lactobacillus bulgaricus*. Activity of less than 50% (i.e. 0% to 50%) is encompassed by or is anticipated by prior art that teaches,

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discloses or suggests no 7 -dehydroxylase activity and bile acid deconjugation activity; or a reference is silent with regard to these activities.

7. To distinguish over the prior art, it is suggested that the claims be directed to a narrower range of bile acid deconjugation activity and 7 -dehydroxylase activity for which the claims are enabled.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

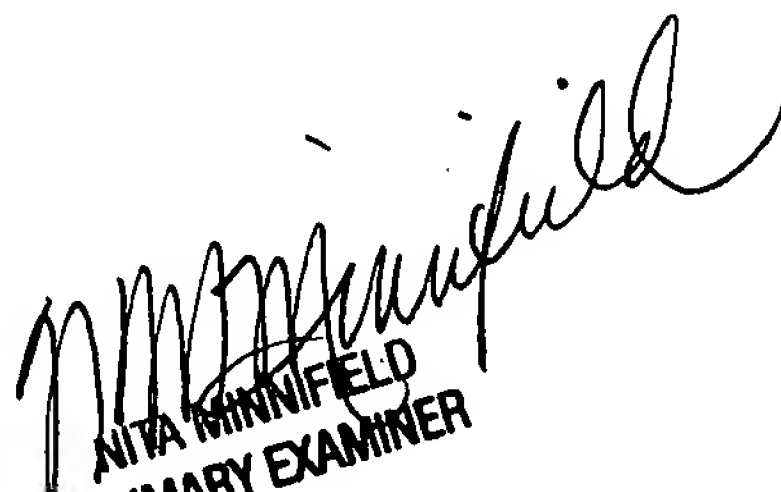
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

March 6, 2000


NITA MINNIFIELD
PRIMARY EXAMINER